PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
GREGORY L. MAYBACK
FELDMAN GALE, P.A.
PO BOX 2480
HOLLYWOOD, FL 33022-2480

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 15 SEP 2005
Applicant's or agent's file reference GLM-1042 PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US04/28530	International filing date (*day/month/year*) 02 September 2004 (02.09.2004)
Applicant BOLTON MEDICAL INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
   1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Brian Pellegrino Telephone No. (703-308-0858

Form PCT/ISA/220 (January 2004) (*See notes on accompanying sheet*)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference GLM-1042 PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US04/28530	International filing date (*day/month/year*) 02 September 2004 (02.09.2004)	(Earliest) Priority Date (*day/month/year*) 03 September 2003 (03.09.2003)
Applicant BOLTON MEDICAL INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
      ☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ Certain claims were found unsearchable (See Box No. II)
3. ☐ Unity of invention is lacking (See Box No. III)
4. With regard to the title,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☐ the text is approved as submitted by the applicant.
   ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract

Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

NEW ABSTRACT

A vascular repair device (1) includes a tubular graft body (10) and a structural framework having at least two stents (20) connected to the graft body. Stents of the structural framework can each be respectively connected to graft body adjacent the proximal and ends and the support member (40) is shorter than the separation distance therebetween to form a gimbal at least at one end. A first stent is connected along an entirety thereof and a second stent is connected at distal apices thereof. Distal apices of the second stent have radii of curvature smaller than proximal apices. A curved longitudinal support member can be connected to the graft body, the support member being substantially symmetrical with respect to the centerline. The support member can be connected to the graft body independent of the structural framework. At least one of the ends of the support member can have a curved longitudinal extremity.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28530

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/06
US CL : 623/1.13
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.13,1.15,1.11,1.16,1.32,1.34,23.54,23.66; 606/191,192,194,198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
text terms: stent graft, guidewire, lumen, curved, delivery, unconnected, catheter, radiopaque

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,355,060 B1 (Lenker et al) 12 March 2002, Figs. 1, 4,6-8, col. 3, lines 44-47, col. 6, lines 39-45	1,2,6,15-17,20,21,24,43,46-48,87-94,96
X	US 6,402,781 B1 (Langberg et al) 11 June 2002, Fig. 3, col. 10, lines 13-16,32-37,40-65, col. 11, lines34-36, col. 12, lines 58-60.	123-125,133-136,138,142-144,150-153,155,159
X	US 5,607,442 A (Fischell et al) 04 March 1997, Figs. 1,2, col. 1, lines 64-67, col. 2, lines 39-42.	68-77,83,84
X	US 5,676,696 A (Marcade) 14 October 1997, Figs. 1,2,4,9 col. 4, lines 41-54,60-65, col. 9, lines 54-61, col. 10, lines 24-32,57-67, col. 16, lines 46-65, col. 17, lines 53-67.	51-70,73,77,83-86
X	US 6,302,907 B1 (Hijlkema) 16 October 2001, Figs. 2B,3, col. 1, lines 49-53,61-65, col. 5, lines 11-15.	1,3,4,7-10,14,16,17,41
X	US 6,524,335 B1 (Hartley et al) 25 February 2003, Figs. 1-3, col. 1, lines 57-63, col. 4, lines 43-49, col. 5, lines 9,10,22-26.	1,20-26,28-40,42

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 July 2005 (08.07.2005)	15 SEP 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Brian Pellegrino Telephone No. 703-308-0858

Form PCT/ISA/210 (second sheet) (January 2004)

Continuation of Item 4 of the first sheet:
The title is too long.

The new title is: Stent graft, delivery system and method of implanting

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
GREGORY L. MAYBACK
FELDMAN GALE, P.A.
PO BOX 2480
HOLLYWOOD, FL 33022-2480

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* 15 SEP 2005
Applicant's or agent's file reference GLM-1042 PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/28530	02 September 2004 (02.09.2004)	03 September 2003 (03.09.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 2/06 and US Cl.: 623/1.13

Applicant

BOLTON MEDICAL INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [X] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized Officer
Brian Pellegrino
Telephone No. 703-308-0858

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/28530

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/28530

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. Citations and explanations:

Please See Continuation Sheet

Claims 123-125,133-136,138,142-144,150-153,155,159 lack novelty under PCT Article 33(2) as being anticipated by Langberg et al. Langberg et al. discloses a method of delivering a prosthesis to a curved vessel using a guidewire, col. 10, lines 41-44. Fig. 3 shows a guidewire lumen having a curved distal portion 80. Figs. 1 and 6 show the curved implantation site. Langberg additionally discloses that the surgeon monitors the delivery of the prosthesis, col. 12, lines 58-60.

Claims 5,11-13,18,19,27,44,45,49,50,78-82,95,97-122,126-132,137,139-141,145-149,154,156-158 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of features in each of the claims.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/28530

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 96-159 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: these claims should be renumbered because there was no claim 95.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/28530

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 3,5,11-13,18,19,27,44,45,49,50,78-82,91,92,95,97-122,126-132,137,139-141,145-149,154,156-158
The opinion as to Novelty was negative (No) with respect to claims 1,2,4,6-10,14-17,20-26,28-43,46-48,51-77,83-90,93,94,96,123-125,133-136,138,142-144,150-153,155,159
The opinion as to Inventive Step was positive (Yes)with respect to claims 5,11-13,18,19,27,44,45,49,50,78-82,95,97-122,126-132,137,139-141,145-149,154,156-158
The opinion as to Inventive Step was negative(NO) with respect to claims 1-4,6-10,14-17,20-26,28-43,46-48,51-77,83-94,96,123-125,133-136,138,142-144,150-153,155,159
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-159
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1,2,6,15-17,20,21,24,43,46-48,87-90,93,94,96 lack novelty under PCT Article 33(2) as being anticipated by Lenker et al. Lenker discloses (Fig. 1) a tubular graft body 20 and a structural framework with at least two stents 14. Fig. 4 shows the vascular repair device has a curved longitudinal support member 42 connected to the graft body independent of the stents. Lenker also discloses the support or runner is made of nitinol or stainless steel, col. 8, lines 27-29,49. Fig. 33 shows a delivery system with a control handle and a control assembly 34 with a hollow catheter or cover 32 connected to the control handle. It can be seen there is also a delivery assembly disposed in the catheter and Fig. 27 shows a shaft 44 having a lumen for a guidewire within the lumen of the catheter, see also col. 7, line 27. The guidewire lumen is curved when inserted in a curved vessel as is shown to be curved in Fig. 27. Lenker additionally discloses the implantation site is a curved portion of a branch vessel off the aorta, col. 9, lines 46-48.

Claims 91,92 lack an inventive step under PCT Article 33(3) as being obvious over Lenker et al. Lenker et al. is explained supra. However, Lenker fails to disclose the guidewire lumen is made of metal. The use of metal, such as stainless steel for guidwire lumens is well known in the art. It would have been an obvious expedient to use steel for the guidewire lumen with the delivery system of Lenker et al. such that it provide a protective lumen to prevent the guidewire from puncturing any portion of the vessel.

Claims 1,4,7-10,14,16,17,41 lack novelty under PCT Article 33(2) as being anticipated by Hijlkema. Fig. 2B shows that the vascular repair device has at least two stents 12i, 12ii and a pre-curved longitudinal support member 21'I connected to the stents. Hijlkema also discloses the device includes a tubular graft body, col. 5, lines 12-14. Fig. 3 shows the support member can extend along the stent and can be construed to be a partial helix. It can be seen that the support members are shorter than the structural framework.

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over Hijlkema. Hijlkema is explained supra. However, Hijlkema fails to disclose the support member as being S-shaped. S-shaped "support members" are well known in the art and provide more flexibility to the stent. It would have been an obvious expedient to incorporate an S-shape in the support member of Hijlkema such that it permits the device to more easily move through tortuous vessels.

Claims 1,20-26,28-40,42 lack novelty under PCT Article 33(2) as being anticipated by Hartley et al. Fig. 1 shows a vascular repair device with a tubular graft body 5 with a structural framework of at least two stents 7,8 connected to the graft body. Fig. 3 shows the device having what can be construed as a curved longitudinal support member 16. Regarding claim 20, Hartley's Fig. 2 can also be interpreted to have at least an outer stent 1 and an inner stent 8 separated from one another. Regarding claim 26, it appears that the support member 16 connected to the graft body does not touch the stents, Fig. 4. With respect to claims 30 and 39, Fig. 2 shows stent 7 having a periodically changing shape with distal apices having a smaller radii of curvature than the proximal apices.

Claims 68-77,83,84 lack novelty under PCT Article 33(2) as being anticipated by Fischell et al. Fischell discloses implanting a stent in a vessel using radiopaque markers to view the device while inserting it in the patient, col. 1, lines 65-67. Fig. 2 shows a pair of opposing radiopaque markers 15 along the longitudinal axis of the stent. Fischell also discloses aligning the device by orienting the

International application No.
PCT/US04/28530

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

device along the longitudinal axis by rotating the device until viewing the markers, col. 3, lines 23-29. The cross-section shown in Fig. 2 can be construed to be D-shaped or oval.

Claims 51-70,73,77,82-86 lack novelty under PCT Article 33(2) as being anticipated by Marcade. Marcade discloses (Fig. 2) a vascular repair device with a tubular graft body 112 with a structural framework 162 connected to the body and a pair of radiopeque markers 148 connected to the graft body. It can be construed that the markers are hemispherical since they are on the tubular graft surface. Marcade discloses the markers are disposed about the circumference such that there are markers opposing one another on opposite sides of the graft, col. 10, lines 65-67. Marcade discloses multiple stents can be used with the graft, col. 15, lines 4-7. Marcade also discloses methods of deploying the graft device using the markers to align it properly within the vessel, col. 16, lines 46-65.